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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,813	03/06/2002	Kelly Huang	JBP-581	8501

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EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,813	HUANG ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-27-06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 11-22 are pending.

2. In light of Applicant's amendments to the claims and subsequent new art rejections being applied, claim 17 is being examined in the current Office Action.

3. The following new grounds of rejections are necessitated by Applicant's amendment filed 1-27-06.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This a new matter rejection.

Applicant has amended the claims by the insertion of measuring irritation in skin by applying to skin a topical skin care product comprising anionic surfactant. However in reviewing where Applicant state they have support, Example 2, is drawn to measuring SLS's, an anionic surfactant, effect on IL-1-alpha levels not eicosanoid levels. While Applicant does having working examples of measuring eicosanoid levels in topical skin care products that have anionic surfactants in them in addition to external aggression, there is no written support in the specification or claims as originally filed for measuring eicosanoid levels in response to only applying a topical skin care product that generically has an anionic surfactant in it.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "to an external aggression or combinations thereof" in lines 9-10, where the preamble only recites topical skin care product comprising anionic surfactant. There is insufficient antecedent basis for this limitation in the claim.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller-Decker et al., (reference AH on the IDS submitted 3-6-02) in view of Perkins et al., 1997, (reference AG submitted in the IDS received 3-6-02).

Mueller Decker et al., teaches that assessing skin irritation is necessary to protect humans from the hazards of topical exposure of environmental, industrial and consumer chemicals. Mueller Decker et al., further discloses an invasive method measuring PGE2 levels in skin blister

fluid as in indicator of skin irritation that has had SLS applied to it in aqua bidest, wherein said PGE2 levels are measured by GC/MS, wherein said levels are measured against a control and wherein IL-1-alpha levels are also measured and wherein said measuring is performed 24 hours after the applying of the topical product.

The claimed invention differs from the prior art teachings by the recitation of using a non-invasive adhesive coated microporous plastic film to collect the skin samples as secretions to detect skin irritation.

However, Perkins et al., specifically teaches the use of Sebutape™, as a non-invasive method for assessing human skin irritation by using an adhesive coated microporous plastic film, in the detection of IL-1-alpha by a non-invasive method to assess human skin irritation even in the absence of visible clinical irritation. Perkins et al., further teaches that said tape can be easily applied in a clinical setter whether on infants, adults or geriatric adults.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to screen for skin irritation by detecting PGE2 and IL-1 alpha, as taught by Mueller-Decker et al., but substitute the use of Sebutape™, as taught by Perkins et al., because Sebutape™ is able to detect molecular mediators of skin irritation without being invasive and being able to detect said compounds prior to visible clinical irritation and because it can be easily applied in a clinical setting whether on infants, adults or geriatric adults.

11. Claims 11, 16 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller-Decker et al., in view of Perkins et al., as applied to claim 11 above, and further in view of Reilly et al, all of record.

Mueller Decker et al., and Perkins et al., have discussed supra. However, Mueller-Decker et al., does teach normalizing PGE2 levels to the level of fat and it also teaches measuring PGE2 by GC/MS.

The claimed invention differs from the prior art by the recitation of normalizing PGE2 levels by protein levels and by measuring PGE2 by EIA.

However, Reilly et al., specifically teaches normalizing PGE2 levels to the level of protein and measuring PGE2 levels by EIA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to be motivated substitute one known method of measuring PGE2 by EIA rather than GC/MS and normalizing PGE2 with one known method, lipid levels for another known method, protein levels.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

April 13, 2006